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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,982	11/19/2003	Binie V. Lipps	FWLPAT019US	6836

7590 08/07/2006
John R. Casperson
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Friendswood, TX 77549

EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,982	LIPPS ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. The Election filed May 30, 2006 in response to the Office Action of May 8, 2006 is acknowledged and has been entered. Claims 1-23 are pending in the application and Claims 22-23 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. It is noted that upon review and reconsideration, claim 21 has been rejoined with Group

1. Claims 1-21 are currently under prosecution.

2. Applicant's election with traverse of Group 1, claims 1-20 is acknowledged. The traversal is on the ground(s) that the inventions are related and therefore are not independent. The argument has been considered and has been found persuasive for the invention of claim 21 but has not been found persuasive for the invention of claims 22-23 because MPEP 802.01 provides that restriction is proper between inventions which are independent or distinct. Here, the inventions of the various groups are distinct for the reasons previously set forth. Further, Applicant appears to be arguing that search of all of the claimed inventions together would not be a serious burden on the examiner because the inventions are related. The argument has been considered but has not been found persuasive because the literature search, particularly relevant in this art, is not coextensive. Different searches and issues are involved in the examination of each group. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

3. Upon review and reconsideration it is found that the elected invention is drawn to the following patentably distinct species.

(1) Claim 1 is generic to a plurality of disclosed patentably distinct species which are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the species are (a) process for determining an

immunological reaction wherein antibodies are not produced as part of the assay as contemplated in the specification, (b) process for determining an immunological reaction wherein antibodies against a colony of cancer cells are produced as part of the assay.

If the species of Group 3(1)(b) is elected, this species is further subject to election of a single disclosed species.

Claims 1 and 4 are generic to a plurality of disclosed patentably distinct species wherein the species are cancer cells with different structures and functions wherein the cancer cells are (a) primary cancer cells as contemplated in the specification, (b) cultured cell line cancer cells.

The species of Group 3(1) is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species which are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the species are (a) assay for binding affinity, (b) assay for titer.

The species of Group 3(1) is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species which are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the saliva samples are (a) unprocessed saliva samples as contemplated in the specification, (b) saliva samples centrifuged to separate out cells and mucin.

(2) Claims 1 and 16 are generic to a plurality of disclosed patentably distinct species which are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the species are (a) determining an immunological reaction against a plurality of proteomic cancer markers from a single cancer type, (b) determining an immunological reaction against a plurality of proteomic cancer markers from different cancer types.

If the species of Group 3(2)(b) is elected, this species is further subject to election of a single disclosed species.

Claim 16 is generic to a plurality of disclosed patentably distinct species which are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the species are (a) combined assay with antibodies from a plurality of cancer types assayed together in a single saliva sample assay, (b) combined assay with antibodies from a plurality of cancer types assayed separately in portions of a saliva specimen.

Claims 1 and 16 are generic to a plurality of disclosed patentably distinct species which are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the species are (a) assay for binding affinity, (b) assay for titer.

Claims 1 and 16 are generic to a plurality of disclosed patentably distinct species wherein the species are antibodies against cancer cells with different structures and functions wherein the cancer cells are (a) primary cancer cells as

contemplated in the specification, (b) cultured cell line cancer cells as contemplated in the specification.

Claims 1 and 16 are generic to a plurality of disclosed patentably distinct species which are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the saliva samples are (a) unprocessed saliva samples as contemplated in the specification, (b) saliva samples centrifuged to separate out cells and mucin as contemplated in the specification.

4. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

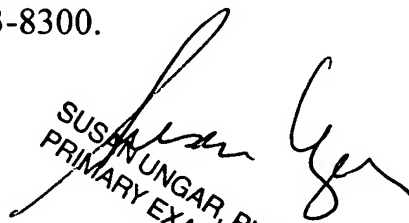
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.


SUSAN UNGAR, PH.D
PRIMARY EXAMINER

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Susan Ungar
Primary Patent Examiner
July 31, 2006

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